K132874
Page 1 of 2

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FEB 21 2014

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(k) Summary

10 February 2014

Submitter of 510(k):

Company name:	Nucletron BV
Registration number:	611894
Address:	Waardgelder 1, 3905 TH Veenendaal, The Netherlands
Phone:	+31 318 557 133
Fax:	+31 318 557 118
Correspondent:	Rudolf Vos

New Device Name:

Trade/Proprietary Name:	LumenCare Azure
Common/Usual Name:	Intraluminal Brachytherapy applicator
Classification Name:	Remote controlled radionuclide applicator system accessory
Classification:	21CFR892.5700 Class II
Product code:	JAQ

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	LUMENCATH APPLICATOR SET	K091598

Description:
The LumenCare Azure is a modification of the Lumencath Applicator Set. It is intended for intraluminal brachytherapy and is used for treatment of the lung and any lumen that allow the insertion of this flexible applicator, e.g. bronchus and bile duct. The applicator consists of a flexible thin catheter and accessories that assist during applicator placement, imaging and treatment. The catheter fits in the working channel of an endoscope. This way, the catheter can be positioned into the treatment area under direct visual control.

The catheter of the LumenCare Azure can be delivered in three variants. These variants only differ in dimensions, i.e. catheter diameter (outer diameter and inner diameter) and total length of the catheter.

The devices are used as accessories to Nucletron afterloaders.

Intended use:

The LumenCare Azure is intended for intraluminal brachytherapy and is used for treatment of the lung or other lumen, e.g. bronchus and bile duct.
The LumenCare Azure is designed to fit in the working channel of an endoscope.

Summary of technological considerations:
The intended use was rephrased to make the wording more consistent, but is essentially the same as the intended use for the cleared device. The catheter is made of another material (which is more kink resistant), the dimensions are similar. All other components are identical.

Summary of testing:
Validation of sterilization processes and biocompatibility is provided. Bench testing (similar to bench testing done to the Legally Marketed Device) shows that the device meets its performance requirements, and that the device performance is equivalent to the Lumencath Applicator Set.

Conclusion:

Nucletron considers the LumenCare Azure to be substantially equivalent to legally marketed predicate device through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Nucletron B.V.
% Mr. Rudolf Vos
QA/RA Engineer
Waardgelder 1, Veenendaal, 3905 TH
THE NETHERLANDS

Re: K132874
Trade/Device Name: LumenCare Azure Set 6F, 150cm, LumeCare Azure Set 5f, 150 cm, and LumenCare Azure Set 5f, 140 cm
Regulation Number: 21 CFR 892.5700
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: JAQ
Dated: January 22, 2014
Received: January 24, 2014

Dear Mr. Vos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

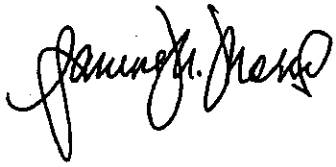
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132874

Device Name: LumenCare™ Azure

Indications for Use:

The LumenCare Azure is intended for intraluminal brachytherapy and is used for treatment of the lung or other lumen, e.g. bronchus and bile duct.

The LumenCare Azure is designed to fit in the working channel of an endoscope.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k) K132874